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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,715	08/14/2001	Moncef Jendoubi	266/226	1686

22249 7590 01/16/2002

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EXAMINER
TRAN, MY-CHAU T

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 01/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/930,715	Applicant(s) JENDOUBI, MONCEF	
	Examiner My-Chau T. Tran	Art Unit 1641	

-- The MAILING DATE of this communication appears on th cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/12/01* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 August 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> The full name of each inventor (family name and at least one given name together with any initial) has not been set forth.

It is improper to include applicant title, "Dr.", as part of applicant first name. Applicant middle name or initial should also be supply.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: "Ab." of figure 1 and "Idf." of figure 2. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: the reference character "3" mentioned in the specification has been used to designate as both normal cells (pg. 13, lines 28) and samples derived from a normal patient (pg. 13, lines 10-11). The reference

character "4" mentioned in the specification has been used to designate as both diseased cells (pg. 13, lines 28-29) and an early stage cancer (pg. 13, lines 11).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) The claim 1 term "biological conditions" renders the claim indefinite since it does not particularly point out what type condition, e.g. HIV or cell lines.

b) Claim 1 is indefinite in the use of the term "biological material" since it is unclear if it a butterfly or a biodegradable polymer.

c) The term "human disease" of claim 4 renders the claim indefinite since it does not particularly point out what type of disease, e.g. leprosy or Crohn's disease.

Claims 2-13 depend from rejected claim 1 and include all the limitation of claim 1 thereby rendering these dependent claims indefinite.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-2, 4-6 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Schlessinger et al. (US Patent No. 5,837,524).

Schlessinger et al. disclosed a method to analyze gene expression. The method comprise of samples of biological material arranged in a discrete compartment (col. 17, lines 23-31), the samples contain gene expression products from at least two distinct biological conditions such as transduction pathways in a cell or promoter regions (col. 8, line 31-38; Table 1; col. 18, lines 11-15), contacting each samples with an antibody (col. 7, lines 42-46; col. 17, lines 31-37; col. 22, lines 31-32), and correlating the reaction between the antibody and the samples (col. 22, lines 31-45). The antibody is a murine polyclonal antibody (col. 28, lines 34-37). The sample of biological material is protein extract (col. 22, lines 7-9; col. 24, lines 36-39). The protein extract is derived from cancer cells or tissue (Table 1 of col. 8-9; col.13, lines 6-3; col. 22, lines 2-11). The method comprise of identifying the expression product of the gene sequence (col. 17, lines 57-60; col. 22, lines 19-23). The method comprise of raising a monoclonal antibody to the expression product of the gene sequence (col. 22, lines 46-52), and determining the polynucleotide sequence of the gene sequence (col. 17, lines 44-47; col. 18, lines 9-15).

8. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Margolis (US Patent No. 6,037,134).

Margolis teaches a method to analyze gene expression. The method comprise of samples of biological material arranged in a discrete compartment (col. 22, line 61-66), the samples

contain gene expression products from at least two distinct biological conditions such as host-expression vector systems (col. 26, line 44-51), contacting each samples with an antibody (col. 15, line 61-65), and correlating the reaction between the antibody and the samples (col. 16, line 7-11). The antibody is a murine polyclonal antibody (col. 16, lines 12-18).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schlessinger et al. (US Patent No. 5,837,524).

Schlessinger et al. reference has been discussed above which fails specifically to recite the use of 100 antibodies. However, Schlessinger et al. disclose using one or more antibodies reacting with the sample. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include a particular number of antibody in the method of Schlessinger et al. in order to detect a varieties of samples.

Since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

13. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Margolis (US Patent No. 6,037,134).

Margolis reference has been disclosed above for a method to analyze gene expression, which does not explicitly disclose the step of repeating the contacting step. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the step of repeating the contacting step in order to screen large number of samples (col. 22, line 61-67 through col. 23, line 1-39).

Margolis also disclosed the differential analysis between normal and disease state (col. 31, line 58-67 and col. 32, line 1-3). The biological condition is cancer (col. 5, line 14-18 and 40-44; col. 9, line 5-21). The biological condition is exposure to a chemical agent (col. 29, line 42-45).

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a) The following prior art teaches gene expression: Gallo (US Patent No. 6,057,132) and Stillman et al. (US Patent No. 6,074,819).

b) The following prior art teaches cell-based assays: Burbaum et al. (US. Patent No. 5,981,207) Barbera-Guillem et al. (US Patent No. 6,251,616) and Taylor (US Patent No. 6,103,479).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

mct
January 14, 2002

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
01/14/02